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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,623	07/10/2003	Hong-Xia Zhang	529642000300	4096

20872 7590 05/12/2005

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,623	ZHANG ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

1. Claims 1-21 are pending.

2. The drawings filed 10 July 2003 are objected to because no details can be made out in Figures 1 and 4.

Claim Objections

3. Claims 2-14, 15-16 and 19-21 are objected to because of the following informalities:

In claims 2-11, line 2, there should be a comma after "1".

In claim 12, line 2, there should be a comma after "11".

In claim 13, line 2, there should be a comma after "12".

In claims 15-16, line 2, there should be a comma after "14".

In claim 19, line 2, "the following" should be deleted.

In claim 20, line 1, there should be a comma after "19".

In claim 21, line 1, there should be a comma after "20".

4. Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-12 are broadly drawn to any non-naturally occurring salt tolerant plant with fruit that has increased potassium levels when the plant is grown in elevated salt conditions

Claims 13-21 are broadly drawn to a plants transformed with any of a multitude of nucleic acids that hybridize to SEQ ID NO:1 and that have any function.

In contrast, the specification only describes plants transformed with SEQ ID NO:1. Applicant does not describe other plants encompassed by the claims, and the structural and functional features that distinguish all such plants from other plants are not provided.

Hence, Applicant has not, in fact, described non-naturally occurring salt tolerant plants within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

7. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants transformed with nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for any non-naturally occurring salt tolerant plant with fruit that

has increased potassium levels when the plant is grown in elevated salt conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any non-naturally occurring salt tolerant plant with fruit that has increased potassium levels when the plant is grown in elevated salt conditions.

The instant specification, however, only provides guidance for transformation of tomato plants with a nucleic acid of SEQ ID NO:1 (pg 26-29) and analysis of plants when grown under increased salt conditions to show that the fruit has increased potassium content (pg 29-31).

The instant specification fails to provide guidance for non-naturally occurring salt tolerant plant with fruit that has increased potassium levels when the plant is grown in elevated salt conditions within the full scope of the claims.

The instant specification fails to provide guidance for where to find nucleic acids that hybridize to SEQ ID NO:1 under the specified conditions or which substitutions to make to make nucleic acids that hybridize to SEQ ID NO:1 and that produce plants with fruit that has increased potassium levels when the plant is grown in elevated salt conditions

One or few amino acid substitutions could dramatically affect the biological activity and the structure-function characteristics of a protein. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are

maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). All these mutated proteins, however, would have at least 95% identity to the original protein. The nucleic acids encoding all these mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO:1. Making all possible single amino acid substitutions in an 538 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19^{538} nucleic acids; these proteins would have 99.8% identity to SEQ ID NO:2. Because nucleic acids that hybridize to SEQ ID NO:1 would encode proteins with many amino acid substitutions, many more than 19^{538} nucleic acids would need to be made and analyzed. Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing nucleic acids that hybridize to SEQ ID NO:1 would require undue experimentation.

As the specification does not describe the transformation of any plant with a nucleic acid that hybridizes to SEQ ID NO:1, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed

therewith, to identify those with fruit that has increased potassium levels when the plant is grown in elevated salt conditions, if such plants are even obtainable.

Furthermore, the specification does not teach where to find or how to make other non-naturally occurring salt tolerant plants with fruit that has increased potassium levels when the plant is grown in elevated salt conditions. Undue trial and error experimentation would be required to screen through all plants to identify those with fruit that has increased potassium levels when the plant is grown in elevated salt conditions, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13-17 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 13 lacks antecedent basis for the limitation "the non-naturally occurring non-halophyte plant ... of claim 12".

Claim 20 lacks antecedent basis for the limitation "the transgene" in line 1.

Claim Rejections - 35 USC § 102 - 35 USC § 103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Gisbert et al (2000, Plant Physiol. 123:393-402) taken with the evidence of Rus et al (2001, Plant, Cell and Environ. 24:875-880) and the instant specification.

Gisbert et al teach tomato plants transformed with a nucleic acid encoding a Na^+/K^+ transporter have increased salt tolerance (pg 395, left column, paragraph 2, to pg 397, right column, paragraph 2).

Rus et al teach tomato plants transformed with a nucleic acid encoding a Na^+/K^+ transporter, and these plants have increased salt tolerance and lower leaf K^+ content (pg 876, right column, paragraph 6, to pg 878, left column, paragraph 1).

The instant specification teaches that tomato plants transformed with a nucleic acid encoding a Na^+/K^+ transporter have increased salt tolerance and lower leaf K^+ content, and also have higher leaf K^+ content (¶87).

The rejection is made because the Examiner cannot determine definitively whether the prior art possesses the unrecited characteristics of fruit that has increased potassium levels when the plant is grown in elevated salt conditions. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

13. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over al-Karaki (2000, J. Plant Nutrition 23:1-8).

al-Karaki teaches non-naturally occurring salt tolerant tomato plants (Tables 2-3).

The rejection is made because the Examiner cannot determine definitively whether the prior art possesses the unrecited characteristics of fruit that has increased potassium levels when the plant is grown in elevated salt conditions. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

14. Claims 1-7 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over West et al (1984, J. Amer. Soc. Hort. Sci. 109:844-851).

West et al teaches non-naturally occurring salt tolerant grape plants (Table 1).

The rejection is made because the Examiner cannot determine definitively whether the prior art possesses the unrecited characteristics of fruit that has increased potassium levels when the plant is grown in elevated salt conditions. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 14, 18-19, 21-32, 53-54 and 56 of copending Application No. 09/271,584.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants, including tomato, transformed with a nucleic acid of SEQ ID NO:1, as claimed in the copending application, are species of the genus of salt-cultivated plants with increased potassium levels in their fruit. Similarly, methods of making the plants and constructs used in the methods, as claimed in the copending application make the instantly claimed plants obvious. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 13 and 37-59 of copending Application No. 10/155,535.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants, including tomato, transformed with a nucleic acid of SEQ ID NO:5, as claimed in the copending application, are species of the genus of salt-cultivated plants with increased potassium levels in their fruit. Similarly, methods of making the plants and constructs used in the methods, as claimed in the copending application make the instantly claimed plants obvious. Additionally, plants, including tomato, transformed with a nucleic acid of SEQ ID NO:5, as claimed in the copending application, are species of the genus of plants transformed with a nucleic acid that hybridizes to the instant SEQ ID NO:1. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-21 of copending Application No. 10/617,624.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid of SEQ ID NO:1, as claimed in the copending application, are species of the genus of salt-cultivated plants with increased potassium levels in their fruit. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-19 of copending Application No. 10/620,061.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid of SEQ ID NO:1, as claimed in the copending application, are species of the genus of salt-cultivated plants with increased potassium levels in their fruit. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Anne R. Kubelik, Ph.D.
April 29, 2005